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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,848	01/11/2002	Ram Dutta Pathak	P30835DIV2C2	9105

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EXAMINER	
PULLIAM, AMY E	
ART UNIT	PAPER NUMBER
1615	

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11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/044,848	Applicant(s) PATHAK ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,5,6 .
4) ☒ Interview Summary (PTO-413) Paper No(s). 10
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of the Information Disclosure Statements, received January 11, 2002, February 11, 2002, and April 19, 2002. Additionally, receipt is acknowledged of the Preliminary Amendment A, received January 11, 2002. Lastly, receipt is acknowledged of the Declaration, Terminal Disclaimer and Preliminary Statement, received May 9, 2002.

Information Disclosure Statement

The information in the information disclosure statement has been considered. The information available as prior art has been cited, acknowledged, and made of record. The remaining information on the information disclosure statement (the Civil Actions) has been considered but it is not made of record, because it is not prior art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,721,723 to Barnes *et al* (hereinafter Barnes). Barnes discloses crystalline paroxetine hydrochloride hemihydrate, processes for its preparation, compositions containing it, and its therapeutic use as an anti-depressant (abstract). Barnes teaches that the drug is usually adapted for oral administration, such as tablet form (c 5, l 49-60). Additionally, Barnes teaches that the

unit dosage form usually contains from 1 to 200 mg of the active ingredient (c 5, l 53-55). Barnes also teaches that suitable carriers may be included. Further, Barnes teaches that the composition can be formulated by conventional methods of admixture such as blending, filing, and compressing.

Claims 16 and 17 are rejected as product by process claims. According to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985). Barnes also teaches that the active ingredient is used for the treatment of depression. Therefore, Barnes anticipates the generic claims to a composition comprising Paroxetine and excipients.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant's have submitted a declaration in an attempt to overcome the rejection over Barnes *et al.*. However, this declaration is found to be unpersuasive. First, in the interview of January 10, 2002 the examiners asked for a declaration which proves that the tablets of the instant claims are patentably distinct from those of the prior art, and that the differences are the result of the dry process described in the claims. Applicant's declaration contains the personal views of the inventor, however it contains no experimental evidence of scientific data. Additionally, there is still no evidence to persuade the examiner that the product described in Barnes is made by a wet

granulation process. As applicant stated in his declaration, "pharmaceutical tablets can be prepared by numerous processes. For example, pharmaceutical tablets can be formulated by wet or dry methods." Further applicant states that there is no direct evidence as to what process was employed by Barnes in making their formulation.

Secondly, in the above mentioned interview, the examiners also asked for a showing that the unexpected results achieved by the claimed tablets occur irrespective of the excipient used. Again, the declaration contains the personal views of the applicant, however it contains to scientific data, or experimental comparisons to show the unexpected results.

Thirdly, there has been no evidence provided to show that pink hue would be detrimental to a pharmaceutical formulation. In *In re Seid*, 161 F.2d 229, 73 USPQ 431 (CCPA 1947), the court found that matters relating to ornamentation only which have no mechanical function cannot be relied upon to patentably distinguish the claimed invention from the prior art. See MPEP 2144.04 I.

Claims 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 92/09281 to Johnson. Johnson discloses the use of paroxetine or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for use in the treatment of senile dementia (abstract). Johnson further teaches that an acceptable salt of paroxetine is paroxetine hydrochloride (p 1, l 34-35). Johnson also teaches that the medicament can be in tablet form for oral administration (p 2, l 29), and may include excipients suitable for oral administration, such as calcium phosphate, magnesium stearate, and sodium starch glycolate (p 3, l 1-8). Johnson

also teaches that the formulation will generally contain between 2 and 1000 mg, more preferably between 30 and 500 mg per dosage form (p 4, l 32-35). Lastly, Johnson teaches that the formulation may be obtained by conventional methods of blending, filling, tabletting, or the like (p 3, l 12-13).

Claims 16 and 17 are rejected as product by process claims. According to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985). Furthermore, Johnson anticipates the limitations of the composition claims, as he discloses a pharmaceutical tablet comprising paroxetine hydrochloride and excipients.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant stated that in the interview, it was concluded that the Johnson reference did not apply to the instant claims. However, the examiner respectfully disagrees. The instant claims are product by process claims, and only require the limitations of the product. Johnson teaches the limitations of applicant's product, and therefore, the limitations of the claims. Additionally, Johnson teaches that the product can be made through typical methods known in the art. In applicant's declaration, it was stated that wet and dry granulation are both well known methods of tablet formulation. Furthermore, there has been no scientific or comparative evidence presented to persuade the examiner that the formulation in the Johnson reference is made by a

process different than the one claimed by applicant. Furthermore, the process by which the formulation is made is insignificant, unless it is scientifically proven that the resulting product is different.

Previously, applicant argued that the processes used to produce the paroxetine tablets sold at the time of the instant invention were formulated using an aqueous granulation process, which results in an unacceptable formulation in that a highly undesirable pink hue was formed on the tablet. However, applicant has provided no support for this comment. Additionally, Applicants argued that Johnson does not discuss the problem or solution focused on by applicant. These arguments are not found to be persuasive for three reasons. First, there is no evidence that the product disclosed by Johnson possesses the pink hue as suggested by applicant. Second, even if the Johnson formulation does contain the pink hue, there is nothing in the claim language to state that the formulation can not have a pink hue. Third, applicant is claiming a composition, not a method of making a composition. As discussed in the original, and above rejections, even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself.

On a different note, applicant states at the bottom of page 4 of the response that Johnson teaches no specific type of formulation process. Then on page 6, applicant states that all of the paroxetine tablets sold at the time of the invention were formulated using an aqueous granulation process. There is no evidence to suggest that the formulation of Johnson is one of the tablets which was marketed at the time of the invention. Furthermore, Johnson does not teach that his formulation is made by wet granulation. This rejection is therefore maintained.

Claims 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 269 303 to Lassen. Lassen discloses a method for treating pain which comprises administering an effective amount of paroxetine or an acceptable salt thereof (abstract). Lassen further teaches that an acceptable salt of paroxetine is paroxetine hydrochloride (p 2, l 14). Lassen also teaches that the medicament can be in tablet form for oral administration (p 2, l 33-36), and may include excipients suitable for oral administration, such as calcium phosphate, magnesium stearate, and sodium starch glycolate (p 2, l 39-44). Lassen also teaches that the formulation will generally contain between 2 and 1000 mg, more preferably between 30 and 500 mg per dosage form (p 3, l 17-20). Lastly, Lassen teaches that the formulation may be obtained by conventional methods of blending, filling, tabletting, or the like (p 2, l 45-46).

Claims 16 and 17 are rejected as product by process claims. According to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985). Furthermore, Lassen anticipates the limitations of the composition claims, as he discloses a pharmaceutical tablet comprising paroxetine hydrochloride with excipients.

Applicant's arguments have been fully considered but are not found to be persuasive. This rejections is maintained for the reasons discussed at the end of the previous rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 269 303 to Lassen or WO 92/09281 to Johnson or US Patent 4,721,723 to Barnes *et al.* as applied to claims 16 and 17 above. Neither Lassen nor Johnson gives a specific example teaching applicant's exact method. However, as stated above, the claims are rejected as product by process claims, because Johnson and Lassen both teach applicant's claimed product. Furthermore, both references teach that the oral tablet may be formulated by any conventional method. One of ordinary skill in the art would have been motivated to create an oral formulation comprising paroxetine and the instantly claimed excipients, based on the teachings of Johnson and Lassen. The expected result would be a successful pharmaceutical formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Lastly, as is stated in applicant's declaration, both wet and dry granulation methods are well known methods for tablet formulation. Furthermore, there has been no evidence provided to persuade the Office that the prior art cited used one method of tableting over another. However, the prior art does not discuss the commercial scale limitation of applicant's claims. However, in *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976), it was determined that "mere scaling up of a prior art process capable of being scaled up, if such were the case, would

not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.) See MPEP 2144.04 IV.

This rejection is therefore maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

aep
May 31, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600